

## § 20.106

## 21 CFR Ch. I (4–1–08 Edition)

(d) Access to all raw data, slides, worksheets, and other similar working materials shall be provided at the same time that the final report is disclosed.

### § 20.106 Studies and reports prepared by or with funds provided by the Food and Drug Administration.

(a) The following types of reports and studies prepared by or with funds provided by the Food and Drug Administration are available for public disclosure upon their acceptance by the responsible agency official:

(1) Quarterly and annual reports of the agency.

(2) External investigations or review of agency needs and performance.

(3) Surveys, compilations, and summaries of data and information.

(4) Consumer surveys.

(5) Compliance surveys.

(6) Compliance programs, except that names of specific firms, the location of specific activities, and details about sampling numbers or sizes shall be deleted until implementation of the program is completed.

(7) Work plans prepared by Food and Drug Administration centers, field offices, and other components, except that names of specific firms, the location of specific activities, and details about sampling numbers or sizes shall be deleted until implementation of the plan is completed.

(b) The following types of reports and studies prepared by or with funds provided by the Food and Drug Administration are not available for public disclosure:

(1) Internal audits of agency needs and performance.

(2) Records relating to the internal planning and budget process.

(3) Legislative proposals or comments prior to submission to Congress.

[42 FR FR 15616, Mar. 22, 1977, as amended at 50 FR 8995, Mar. 6, 1985]

### § 20.107 Food and Drug Administration manuals.

(a) Food and Drug Administration administrative staff manuals and instructions that affect a member of the public are available for public disclosure. An index of all such manuals is available by writing to the Freedom of Information Staff (HFI-35), Food and

Drug Administration, rm. 12A-16, 5600 Fishers Lane, Rockville, MD 20857, or by visiting the Freedom of Information Public Reading Room, located in rm. 12A-30 at the same address. The index and all manuals created by the agency on or after November 1, 1996, will be made available through the Internet at <http://www.fda.gov>.

(b) Manuals relating solely to internal personnel rules and practices are not available for public disclosure except to the extent that the Commissioner determines that they should be disclosed pursuant to § 20.82.

(c) All Food and Drug Administration action levels which are used to determine when the agency will take regulatory action against a violative product, limits of sensitivity and variability of analytical methods which are used in determining whether a product violates the law, and direct reference levels above which Food and Drug Administration field offices may request legal action directly to the office of the General Counsel, are available for public disclosure.

[42 FR 15616, Mar. 22, 1977, as amended at 46 FR 8457, Jan. 27, 1981; 46 FR 14340, Feb. 27, 1981; 68 FR 25287, May 12, 2003]

### § 20.108 Agreements between the Food and Drug Administration and other departments, agencies, and organizations.

(a) All written agreements and understandings signed by the Food and Drug Administration and other departments, agencies, and organizations are available for public disclosure.

(b) A permanent file of all such agreements and understandings is available for public review during working hours in the Food and Drug Administration's Freedom of Information Public Room.

(c) All such agreements and understandings shall be published in the FEDERAL REGISTER, except those agreements and memoranda of understanding between FDA and State or local government agencies that are cooperative work-sharing agreements. In lieu of publication of the complete text of these agreements and understandings, FDA will publish in the FEDERAL REGISTER periodically, but not less than once every 2 years, a notice